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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,238	07/14/2003	Chun Li	1401S	8966
7590		04/17/2006	EXAMINER	
Donald W. Wyatt		EBRAHIM, NABILA G		
Cell Therapeutics, Inc.		ART UNIT		
Suite 400		PAPER NUMBER		
501 Elliott Avenue West		1618		
Seattle, WA 98119		DATE MAILED: 04/17/2006		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,238	LI ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/14/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt is acknowledged of Information Disclosure Statement filed on 7/14/03.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hausheer et al. US 5,468,754 (hereinafter "Hausheer") in view of Runge US 4,485,093 (hereinafter "Runge").

Hausheer teaches compounds 11-hydroxy-7-ethyl camptothecin and 11-hydroxy-7-methoxy camptothecin are active anticancer compounds, which are poorly soluble in water composition for the purpose of inhibiting the growth of cancer cells (abstract). Hausheer also teaches method of treatment of cancer in humans with convergent

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therapy or combination therapy. This claimed method comprises additional drugs selected from the group consisting of, but not limited to, carmustine, cis-platinum, carboplatin, iproplatin (col. 24, lines 18-35). The patent discloses different types of cancers to be treated by the composition like lung, ovarian, colon, and breast cancer (see table 1).

Hausheer does not teach polyglutamic acid to enhance water solubility of the drug.

Rung teaches a water soluble immunotoxin conjugate consisting of arsanilic acid, polyglutamic acid, and a tumor specific antibody wherein: (1) polyglutamic acid having a molecular weight from about 2,000 to about 35,000 covalently binds the antibody and the arsanilic acid via carboxyl groups on the polyglutamic acid; and (2) the arsanilic acid is present in a tumor toxic amount and a method of treatment of the cancer with the disclosed composition (claim 1, 5). The disclosed molecular weight overlaps with the values recited in claims 5-7 of the instant application.

With regard to claims 8, and 9, which recite the percentage of camptothecin in the composition it is known that, once a method of using a compound or a drug is known it is within the skill of the skilled artisan to determine the optimum amounts to use and the optimum end points in using the compound or the drug.

Accordingly, it would have been obvious to one skilled in the art to expand the knowledge of Hausheer and use polyglutamic acid to render the camptothecin into water-soluble drug to facilitate its usage since Hausheer disclosed the problem of insolubility of the drug and Runge gave the solution for the problem by using

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polyglutamic acid to render compositions water-soluble (col. 4, lines 28-33) with an expectation of have water-soluble camptothecin.

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hansen et al. US 5443953, which describes that researchers have investigated the use of a water-soluble polymeric molecule as an intermediary for the indirect conjugation of the camptothecin. Such polymers include poly-glutamic acid.

Correspondence

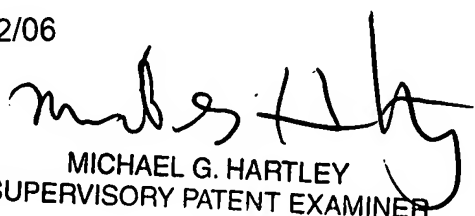
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nabila Ebrahim

4/12/06


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER